

<div data-bbox="131 75 955 287" data-label="Text"> <p>(estradiol benzoate) Microencapsulated Estradiol Benzoate Suspension Implant For Steers and Heifers Fed in Confinement for Slaughter Manufactured by a non-sterilizing process</p> </div> <div data-bbox="323 331 759 411" data-label="Text"> <p>Celerin™</p> </div> <div data-bbox="466 442 616 575" data-label="Image"> </div>			
<div data-bbox="131 636 933 730" data-label="Text"> <p>This package consists of two vials, one vial containing 50-20mg doses of estradiol benzoate microspheres and one vial containing 50mL of diluent.</p> </div> <div data-bbox="131 765 448 795" data-label="Text"> <p>For Use in Aimals Only</p> </div> <div data-bbox="131 830 909 994" data-label="Text"> <p>Description: Celerin™ (estradiol benzoate) contains estradiol benzoate in Theraphase™ microspheres. The microspheres have been designed to release estradiol benzoate at a controlled rate to increase rate of weight gain and improve feed efficiency.</p> </div> <div data-bbox="131 1143 256 1261" data-label="Image"> </div> <div data-bbox="589 1143 952 1268" data-label="Text"> <p>Manufactured by PR Pharmaceuticals, Inc. 1716 Heath Parkway Fort Collins, Colorado 80524</p> </div> <div data-bbox="131 1386 323 1411" data-label="Text"> <p>65-20500/00/0603</p> </div> <div data-bbox="631 1386 988 1411" data-label="Text"> <p>NADA 141-040, Approved by FDA</p> </div>	<div data-bbox="1071 636 1504 795" data-label="Text"> <p>Read enclosed package insert and use as directed. Store under refrigerated temperatures between 36° and 46°F (2° and 8°C).</p> </div> <div data-bbox="1071 843 1452 873" data-label="Text"> <p>Avoid heat and direct sunlight.</p> </div> <div data-bbox="1071 913 1468 1009" data-label="Text"> <p>Exposure to excessive heat and direct sunlight will damage product integrity.</p> </div> <div data-bbox="1077 1166 1178 1195" data-label="Text"> <p>Lot No.:</p> </div> <div data-bbox="1077 1261 1211 1291" data-label="Text"> <p>Exp. Date:</p> </div> <div data-bbox="1046 1390 1529 1411" data-label="Text"> <p>Patent No's: US 5,288,496 US 5,401,507 US 5,427,796</p> </div>	<div data-bbox="1944 597 2127 619" data-label="Text"> <p>NDC XXXXXXXXXX</p> </div> <div data-bbox="1965 627 2111 760" data-label="Image"> </div> <div data-bbox="1818 781 2252 860" data-label="Text"> <p>Celerin™</p> </div> <div data-bbox="1626 904 2447 1118" data-label="Text"> <p>(estradiol benzoate) Microencapsulated Estradiol Benzoate Suspension Implant For Steers and Heifers Fed in Confinement for Slaughter Manufactured by a non-sterilizing process</p> </div> <div data-bbox="1629 1144 2441 1238" data-label="Text"> <p>After mixing, Celerin™ suspension is ready to administer. This powder will provide a suspension of Theraphase™ microspheres containing 20mg/mL estradiol benzoate.</p> </div> <div data-bbox="1648 1298 2423 1397" data-label="Text"> <p>Contains 1 gram estradiol benzoate (50-20mg doses). NET WEIGHT 5.0 GRAMS 16-00020</p> </div>	<div data-bbox="2533 619 3009 869" data-label="Text"> <p>Indications: Celerin™ (estradiol benzoate) is indicated for increase rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter. Do not use in veal calves, calves intended for reproduction, or calves less than 30 days old.</p> </div> <div data-bbox="2527 913 3027 1314" data-label="Text"> <p>Warning: Administer the suspension subcutaneously in the ear only. Any other location is in violation of Federal Law. Do not attempt to salvage this site for animal feed or human use. A withdrawal period has not been established for this product in pre-ruminating calves. Do not use in calves to be processed for veal.</p> </div> <div data-bbox="2591 1352 2975 1411" data-label="Text"> <p>Keep out of reach of children. Use only as directed.</p> </div>
		<div data-bbox="1812 1479 2243 1651" data-label="Image"> </div> <div data-bbox="1947 1656 2102 1677" data-label="Text"> <p>659101XXXXXX</p> </div>	

61-50000/00/0603	See package insert for mixing and use directions. Store under refrigerated temperatures between 36° and 46°F (2° and 8°C).	Manufactured by PR Pharmaceuticals, Inc. 1716 Heath Parkway Fort Collins, CO 80524	NDC XXXXXXXXX
Lot No.: Exp. Date:			<div>Celerin™</div> <div>(estradiol benzoate)</div> <div>Microencapsulated Estradiol Benzoate Suspension Implant</div> <div>For Steers and Heifers Fed in Confinement for Slaughter Manufactured by a non-sterilizing process 50-20 mg doses to be suspended in 50 mL of diluent</div> <div>NADA 141-040, Approved by FDA</div>

61-50110/00/0603	See package insert for mixing and use directions. Store under refrigerated temperatures between 36° and 46°F (2° and 8°C).	Manufactured for PR Pharmaceuticals, Inc. 1716 Heath Parkway Fort Collins, CO 80524	NDC XXXXXXXXX
Lot No.: Exp. Date:			<div>STERILE DILUENT</div> <div>For Use With Microencapsulated Estradiol Benzoate Suspension Implant</div> <div>50 mL for suspension of 50 doses</div> <div>NADA 141-040, 141-041, Approved by FDA</div>

NDC XXXXXXXXXX



1716 Heath Parkway
Fort Collins, Colorado 80524

Celerin™

(estradiol benzoate)

Microencapsulated Estradiol Benzoate
Suspension Implant

Manufactured by a non-sterilizing process



659101XXXXXX

20 X 5.0 GRAMS

(This case contains 20 units.
Each unit contains 50 doses
at 20mg EB per dose)

Store under refrigerated temperatures between 36° and 46°F (2° and 8°C).
Avoid heat and direct sunlight.

61-50010/00/0603

NADA 141-041, Approved by FDA

Lot No.:
Exp. Date:

Celerin™

(estradiol benzoate)

Microencapsulated Estradiol Benzoate

Suspension Implant

Manufactured by a non-sterilizing process

For Use in Animals Only

DESCRIPTION: Celerin™ contains 20mg estradiol benzoate per dose in Theraphase™ microspheres. Each dose consists of a 1mL suspension of the programmed release microspheres. The microspheres have been designed to release estradiol benzoate at a controlled rate in order to increase rate of weight gain and improve feed efficiency.

This package consists of two vials, one vial containing estradiol benzoate microspheres (powder) and one vial containing diluent.

The Celerin™ vial contains estradiol benzoate in 85:15 Poly D,L - Lactide Polymer.

The diluent vial consists of carboxymethylcellulose sodium, USP 2.5%; methylparaben, NF 0.18%; water for injection, USP qs.

Addition of the diluent to the powder results in a suspension ready for use.

INDICATIONS: Celerin™ (estradiol benzoate) is indicated for increased rate of weight gain and improved feed efficiency in steers and heifers fed in confinement for slaughter.

Do not use in veal calves, calves intended for reproduction, or calves less than 30 days old.

DOSAGE AND ADMINISTRATION: Important - Read and follow instructions as illustrated using careful aseptic technique. Never take short cuts at the expense of cleanliness.

Administer 1 dose of the suspension subcutaneously in the ear only. A 16 to 20 gauge needle is recommended. For improved feed efficiency in steers and heifers and increased rate of weight gain in heifers, administer 20mg (1mL) of this suspension.

For increased rate of weight gain in steers, administer 10mg (0.5mL) of the suspension.

The use of 20mg (1mL) in steers does not provide additional rate of weight gain improvement over 10mg (0.5mL).

Agitate vial between administration of doses.

Administer the product with a suitable multi-dose syringe.

MIXING INSTRUCTIONS: Using normal precautions for sterility and safety, draw the entire contents of the liquid diluent into a transfer syringe. Empty contents of transfer syringe into glass vial containing the powder. Mix diluent and powder until all product is suspended. Once mixing has occurred, the suspension should be used within 72 hours. Store under refrigerated temperatures between 36° and 46°F (2° and 8° C). Avoid heat and direct sunlight. Exposure to excessive heat and direct sunlight will damage product integrity.

Do not dose the animal using the transfer syringe or needle.

USE INSTRUCTIONS:



Restrain the Animal.

Accuracy of administration as well as safety to handler is best achieved by restraining animal in a squeeze chute using head restraint.

Prepare the Administration Site.

Scrub the backside of the ear (administration site) using a topical germicidal solution.

Administration Site.

1 dose should be administered beneath the skin in the backside of the middle one third of the ear as illustrated in the drawing. Location for insertion of the needle is a point near the tip of the ear and a needle length away from the intended deposition site. Avoid injuring the large arteries, veins and cartilage of the ear. Damages to large blood vessels may cause loss of the administered dose.



Diagram of the back of the ear. Note the blood vessels. Avoid injection into vessels. Inject in shaded area

Insert the Needle.

Firmly grasp the ear with one hand. With the other hand, insert needle point through the skin and ease forward on a lateral plane until the length of the needle is under the skin. Administer 1 dose.



Post Administration.

Remove the needle and place thumb on the point of the needle insertion site. Continue to apply pressure as you slide your thumb forward from the point of insertion dispersing the fluid under the skin.

WARNING: Administer the suspension subcutaneously in the ear only. Any other location is in violation of Federal Law. Do not attempt to salvage this site for animal feed or human use.

A withdrawal period has not been established for this product in pre-maturing calves. Do not use in calves to be processed for veal.

Keep out of reach of children.

ADVERSE REACTIONS: In clinical studies, no significant adverse reactions were observed.

PRECAUTION: Inadvertent intra-arterial injection of solutions intended for subcutaneous injection in the bovine ear may cause sudden death. This effect has not been studied for this product.

Store under refrigerated temperatures between 36° and 46°F (2° and 8° C).

Avoid heat and direct sunlight. Exposure to excessive heat and direct sunlight will damage product integrity. Suspension should be used within 72 hours.

HOW SUPPLIED: Each package contains one vial of microencapsulated estradiol powder and one vial of sterile diluent for suspension. The entire package constitutes 50 X 20 mg doses of estradiol benzoate.

Manufactured by:
PR Pharmaceuticals, Inc.
1716 Heath Parkway
Fort Collins, Colorado 80524

Celerin™ and Theraphase™ are trademarks of PR Pharmaceuticals Inc.